bullet would. So it would be "the magnitude of correction diminishes over time." The next bullet: "The proportion of intended correction retained beyond 12 months is undetermined."

DR. SUGAR: Is there a second to that?

DR. GRIMMETT: Did she accept the amendment?

DR. SUGAR: Okay, I guess you can -- her motion was a not seconded --

DR. WEISS: Jayne Weiss. So just to clarify, you would agree with CK treatment for the temporary reduction of spherical hyperopia and then everything else that I mentioned stayed the same except for the last two bullets, the magnitude of correction diminishes over time and the proportion of intended correction retained beyond 12 months is undetermined. I would second that.

DR. SUGAR: Discussion? Dr. Pulido?

DR. PULIDO: Jose Pulido. Again, my concern is the last two bullets have nothing to do with indications. It's labeling. And by putting "temporary" you already have taken care of the last two bullets and you can -- I would rather have that shifted -- those last two bullets some modification of the last two bullets shifted over to the labeling.

DR. SUGAR: Other comments?

MR. McCARLEY: Yes, may I suggest that we

keep the first three bullets as they are and simply have a footnote at the word "reduction" and indicate the last two items with some wordsmithing to take out the percentage and so forth, so there's a clarification of what reduction of spherical hyperopia means and then again include this language in the labeling portion of it.

DR. SUGAR: So you're not including the word "temporary" or are you including the word "temporary"?

MR. McCARLEY: I am not. I am defining it with the use of the last two paragraphs. I would also -- yes, I would also include the word "temporary."

DR. SUGAR: Okay.

MR. McCARLEY: But I would do it as a footnote along with the last two points.

DR. SUGAR: Okay. Certainly that's gentler. Further discussion of that?

I think that we need to have the motion -- I guess we're still discussing a motion that's been seconded and the discussion has suggested that the last two bullets be eliminated from the indications and that the word "temporary" be included, although a suggestion has been made that the "temporary" be footnoted and the other two things be footnoted.

I'd like to ask our expert on footnoting to discuss this. Mike? Dr. Grimmett, the footnote expert.

For those of you who didn't read his review, it was highly footnoted.

DR. GRIMMETT: I would, if the word "temporary" is going to be used and the pro for the word "temporary" is that it's easily understandable by the consumer. It's easily recognizable. If the word "temporary" is going to be used, I would put it in the first sentence. I wouldn't footnote it. It's either there or not. I wouldn't put it down, but the word "temporary", I agree with Dr. Pulido that the last two bullets, the word "temporary" replaces those. You're saying the same thing in a different way. I don't think you need to double say it. You either say "temporary" or you say the last two bullets, one or the other.

DR. SUGAR: Jayne?

DR. WEISS: Jayne Weiss. I think I could agree with that because it wold be easily understandable, succinct and the other two statements could be put in labeling, if necessary. I would like the word "temporary" though, not to be footnoted because I think it makes it less clear, less obvious and less understandable.

DR. SUGAR: Okay, this is Tim's motion? Am I correct? Whose motion is it?

DR. WEISS: Actually, Tim's was an amendment to mine and Jose's was an amendment to Tim's, so I think

we're at Dr. Pulido's at this point.

DR. SUGAR: So you've restated your motion that it's the first three bullets with the word "temporary" added?

DR. WEISS: Yes.

DR. SUGAR: Is there any additional confusion? Any additional discussion?

Please.

DR. MATHERS: This is going to be seen as one way of handling this problem. We might also consider a different motion, but we're going to vote on this motion now as it stands, is that right?

DR. SUGAR: There's a motion on the floor that needs to be dealt with and then we could proceed with whatever other motions seem appropriate.

So we're going to vote on this, yes. And I think it's now appropriate to vote. All those in favor of the motion, signify by raising their hand?

MS. THORNTON: Wait, could you just read --

DR. SUGAR: Yes, the motion is the indication for use is CK treatment for the temporary reduction of spherical hyperopia in the range of +.75 to +3.25 diopters of cycloplegic spherical hyperopia; -3.75 diopter or less of refractive astigmatism, +.75 to +3.00 diopters of

cycloplegic spherical equivalent in patients with less than .50 diopter difference between preoperative manifest and cycloplegic refraction who are 40 years of age or older.

[Vote taken.]

All those in favor of motion? Seven.

All those opposed? Two.

The motion carries.

MS. THORNTON: Wait.

DR. SUGAR: Am I wrong? We have 12.

MS. THORNTON: We have 10 votes all together. Could you raise your hands?

DR. SUGAR: There are supposed to be 12 people and there were 7 and 3.

MS. THORNTON: Okay, sorry.

DR. SUGAR: Seven to three. I abstained.

DR. ROSENTHAL: What was the tally?

DR. SUGAR: Seven to three. We now move on to specifying the conditions because we now have the indication. We've specified the conditions and I'd like a motion concerning -- I'm doing it wrong.

MS. THORNTON: The condition that you just discussed was the change in indication. The next condition that you're going to discuss is probably a labeling going on into your labeling. But the change in indication is one of the conditions of the approval. I just wanted to

clarify that.

DR. SUGAR: One of the problems we get into is wordsmithing the words, concerning the wordsmithing of the other words, but additional conditions.

DR. GRIMMETT: Mike Grimmett. There are some additions to the labeling list that I provided that will be a separate consideration because I don't have them written down. Did you write them down, Dr. Weiss?

DR. WEISS: I wrote them down as you were commenting.

DR. GRIMMETT: Okay. I make a motion to include the labeling issues as I've typed in my sheet dated November 30th with the following modification: the No. 10, we were going to change the reduction of to include statement regarding the spectacle or contact lens dependence and No. 13 we just dealt with, so eliminate No. 13.

If I could make a motion that those following labeling suggestions be accepted.

DR. SUGAR: Is there a second?

DR. ROSENTHAL: Rosenthal. Could you just -- I don't want you to go through all of the -- if you could just go through the category, you know --

DR. GRIMMETT: Sure.

DR. ROSENTHAL: Labeling issues relating to

blah, blah, blah.

DR. GRIMMETT: Sure.

DR. ROSENTHAL: So we can have it on record.

MS. THORNTON: Read the complete list as you have discussed and are adding on the complete list into the record, please.

DR. ROSENTHAL: I'll just clarify with Nancy Pulowsky. We don't need to go over every single one, but I think the general idea of --

MS. THORNTON: Right, right.

DR. SUGAR: He can't just say number 1, number 2, number 3?

DR. GRIMMETT: Labeling issues, No. 1, best corrected visual acuity loss greater than or equal to two lines.

No. 2, issues related to subjective symptom data.

No. 3, issues related to inductive of cylinder data.

No. 4, data regarding loss of incorrect visual acuity with induced cylinder.

No. 5, data or statement regarding cylinder axis shifts.

No. 6, predictability data.

No. 7, statement regarding or data regarding post-operative standard deviations of the mean being wider than the pre-op standard deviation of the mean refraction.

No. 8, statement regarding decreased efficacy as the level of pre-op hyperopia increases.

No. 9, statement regarding that the procedure is refractively unstable.

No. 10, statement regarding the spectacle of contact lens dependence following the procedure.

No. 11, a statement regarding rates of dissatisfaction and quality of vision improvement.

No. 12, a statement regarding lack of retreatment data.

DR. SUGAR: And that has been seconded?

DR. WEISS: I'll second that.

DR. SUGAR: Okay. And are there amendments to the motion?

Jayne and then Jose.

DR. WEISS: Jayne Weiss. I would just add some amendment as I was scribing the suggestions that have been added to this point, one being I think Dr. Pulido's recommendation that implantable electrical devices are contraindications for this procedure. I think Dr. Pulido also suggested that the effect in patients with narrow angles is not known.

Dr. Bradley had wanted labeling to include a better description of the procedure for the patient, including the fact that it involved needle placement in the cornea and the fact that data beyond 12 months is not available at this point.

DR. SUGAR: Was there also something about over-correction and the word "gentle heating."

DR. WEISS: Yes, Jayne Weiss. I did leave out my suggestion which is that the patient be informed that initially there would be an overshoot or over correction and that it might take 6 to 9 months before most of the result is reached and also Dr. Bradley's suggestion that the word "gentle heating" be removed.

DR. SUGAR: Is there a second to the

amendment?

Jose, do you have more to add?

DR. PULIDO: No, I second her appended amendment.

DR. SUGAR: Is there discussion of the motion with its 17 points? All those in favor of the listed additional conditions, signify by raising their hand?

DR. HO: There's a comment over there.

DR. SUGAR: I'm sorry, please.

DR. MATOBA: Yes, Alice Matoba. My comment was simply that Dr. Weiss' last addition that the data, we do not have data after 12 months. That should be placed in 9 so that when we say it's unstable, it's understood that we only have data up to 12 months and we don't know whether it's stable or unstable after that time period.

DR. SUGAR: Do you accept that, Jayne?

DR. WEISS: Yes, I do.

DR. SUGAR: And Jose?

DR. PULIDO: I would, yes.

DR. SUGAR: So Ralph, has it been adequately stated?

DR. ROSENTHAL: You've included all the labeling issues?

DR. SUGAR: I believe so. Are there additional labeling issues that anyone would like to add?

Yes?

DR. HUANG: Andrew Huang. I'd like to add. I think we should probably clarify one of the labeling indications that the higher amount of hyperopia has less effect, but you probably included it in one of the points.

DR. GRIMMETT: I believe that's No. 8.

DR. SUGAR: Okay.

DR. GRIMMETT: I included it by stating three pieces of information that support that tenet.

DR. SUGAR: Okay, is there any confusion about the motion?

This condition with its numerous points is now up for vote. All those in favor, signify by raising their hand.

[Vote taken.]

DR. SUGAR: Those opposed? Those abstaining? So none opposed, one abstaining, nine in favor.

I believe that we have covered everything that's been presented thus far. Is there anything that we have missed? Are there any additional motions

that anyone would like to make or any additional modifications?

Please?

DR. HUANG: I would like to recommend to the sponsor to continue to monitor the patient beyond 24 months.

DR. SUGAR: Okay, a suggestion has been made that we request additional follow-up data from the sponsor.

DR. ROSENTHAL: Could you put that in as a motion?

DR. SUGAR: As a condition of approval which is clarified to us as to what exactly you want.

DR. SUGAR: So if we could form that up a little better, go ahead.

DR. GRIMMETT: Well, I have a question first. Mike Grimmett. Isn't it tacitly assumed that since the study was designed for 24 months, they're at least going to go to 24 months and submit the data?

No?

DR. SUGAR: It doesn't hurt to ask for it anyway, I think.

DR. ROSENTHAL: I don't think you can tacitly assume anything.

DR. GRIMMETT: Okay.

DR. ROSENTHAL: We're asking for your recommendations.

DR. GRIMMETT: I'd like to make the first motion that this study be completed to the 24-month interval with submission of the data for FDA review.

DR. SUGAR: As a condition for approval or subsequent to approval?

DR. GRIMMETT: Post-market evaluation that the study simply needs to be continued and not stopped at this time point.

DR. SUGAR: Was that the sense of your motion?

DR. HUANG: Yes.

DR. SUGAR: So the motion has been made and effectively seconded, is that fair?

DR. GRIMMETT: Yes.

DR. SUGAR: Discussion? All those in favor?

[Vote taken.]

DR. SUGAR: Nine. Opposed? Abstaining? One.

Any additional conditions or motions?

DR. McMAHON: Would it be reasonable to ask the sponsor to supply data on retreatments, post-market study?

DR. SUGAR: I guess we can discuss that as an issue, not as a motion. One of the conditions we had was the statement that there is lack of retreatment data. Whether we -- and we can say what we want, but whether we want to make that a condition for the approval or not, I think is the issue at hand here. Does anyone -- are you suggesting that as a motion, Tim, or not?

DR. McMAHON: It's an issue that has me a little bit concerned and I guess I'd want this erred before we leave as to whether the rest of you feel the same way and want to make that a higher priority issue and a part of the approval process.

DR. SUGAR: My question, if it's appropriate for me to comment is whether -- we would love to have that information. I presume the sponsor would too. Whether it's appropriate in approving what's been presented to us or not approving what's been presented to us to ask for that or not, I don't know. I don't -- this process --

DR. McMAHON: That's why I raised it as a question is I don't know if it's an appropriate question.

DR. SUGAR: Ralph?

DR. ROSENTHAL: We're asking for a Panel

recommendation and I really don't want to comment what's appropriate or what's inappropriate. I mean you have to consider least burdensome issues and you have to consider what is scientifically required and you have to consider what is necessary to label the PMA.

DR. SUGAR: Dr. Ho, did you want to comment?

DR. HO: In my view, I think that's a very important issue, but I think that I would not require it as a condition of approval of this particular PMA. I think there are potentially incentives for the company and for the public, later on, as a separate study for that to be performed, but I would not view that as a condition for approval of this PMA.

DR. SUGAR: Is there additional discussion of the nonmotion? Are there any additional issues? Please.

DR. GRIMMETT: Mike Grimmett. We just discussed and approved a motion for post-market evaluation to 24 months. I think that assumes that stability will be at least established or reached during that time interval. I just would like to raise the point what if stability is not reached by 24 months? Would people be in favor of having the study

continued longer or what's the sense about that?

DR. SUGAR: Jose?

DR. PULIDO: Jose Pulido. I don't think so because the 2-year point we're doing just to see if it continues to be a temporary -- to leave it as a temporary situation. If at two years the company sees that there still hasn't been any stability, then they can't come back to us and say well I want to change this. So it's now on the company's side to determine whether they want to continue it past the 2-year point or not.

DR. SUGAR: Please.

MR. McCARLEY: I'd simply suggest that if you're going to ask for the 2-year data as a condition of approval, then the company be permitted or required, whichever way you want to look at this, to put that in the labeling when that information becomes available and it's been reviewed by FDA because then you're going to know what you want to know now and it may be in their favor. It may be still a question.

DR. SUGAR: The sense I have is that that's implied in our motion, is that correct?

MS. THORNTON: Yes.

DR. MATOBA: I think we're ready for voting on the main motion with its conditions,

including the changes in indication, the labeling changes and the continuation of the study for 24 months. Is there anything we have missed?

So that motion, I guess, was the original motion, so we need to vote on the package. And no additional motion needs to be made, correct?

So can I say all in favor?

MS. THORNTON: Yes.

DR. SUGAR: Thank you. All those in favor, signify by raising their hand? All those opposed? One opposed.

[Vote taken.]

DR. SUGAR: So the motion carries and we now poll the Panel for a comment on their vote. We should be in with Dr. Pulido.

DR. PULIDO: Jose Pulido. I voted approvable with conditions. And I believe that this is a device that can temporarily and unpredictably diminish hyperopia and with these conditions that shows that is the case.

DR. McMAHON: Tim McMahon. I voted for approval with conditions for essentially the same reasons.

DR. BRADLEY: Arthur Bradley. I voted against approval. Basically, I think the CK procedure

has been shown to be unreliable, inaccurate and unstable. However, the accuracy and reliability did improve during the first year post-op and results from previous thermal keratoplasty procedures make it likely that the rate -- sorry, make it likely that the rate of change of regression will decline within the second year. Therefore, I feel that it's premature at this time to approve this device and I would like to wait until evidence of stability before voting for approval.

DR. WEISS: Jayne Weiss. I voted approvable with conditions because I think the sponsor has satisfactorily met the criteria set forth by FDA. I have concerns about the shifting axis and amount of astigmatism, but that will be addressed in patient labeling. I also have concerns about the fact that stability had not been reached at 12 months, but I think the consumer is protected by indicating at the present time this is a temporary correction of hyperopia.

DR. GRIMMETT: Michael Grimmett. I unenthusiastically voted approvable with conditions as I believe the procedure is reasonably safe, yet only marginally effective. I'm uncomfortable with the lack of stability of the procedure, but with the conditions

and labeling conditions that we approved, I feel the consumer should have an adequate chance of achieving the appropriate information in order to make an informed consent about this procedure.

DR. MATOBA: Alice Matoba. I voted for approval with conditions. I think the procedure is reasonably safe and fairly effective and the sponsors did meet the criteria set by the FDA.

DR. HO: Allen Ho, approvable with conditions. I think that this a safe procedure. Its efficacy seems to be marginal to fair in my view. I think they've met the criteria set forth by the guidelines of the FDA a priori and with the conditions that are specified in the labeling, I'm comfortable with that.

DR. JURKUS: Jan Jurkus. I voted approvable with conditions since the conditions that we had so thoroughly discussed adequately reflected my concerns with this product.

DR. MATHERS: Bill Mathers. I voted approvable with conditions. I believe that the device fulfills the FDA's requirements and is reasonably effective and reasonably safe and that the labeling will indicate to the public how it can understand the proper use of the device.

DR. HUANG: Andrew Huang. I voted for approval with conditions based on the fact that I think this is a relatively safe procedure, yet the effect is unsustained. But I do believe that with the condition provided by the Panel that physicians, as well as the patient, now can make an informed decision on this procedure.

DR. SUGAR: Thank you. PMA P010018 then has been dealt with.

I'd like to just make a statement. This is the end of my tenure on the Committee and as Chair of the Committee, even though it was brief, I went to the American Academy of Ophthalmology a couple of weeks ago and there was a videotape presented by Bobby Osher that was titled "FDA or DWB", something like that, FDA meaning you guys or DWB which is Doing What's Best and I having come into this a little bit skeptically have learned that the people here are doing what is best under the circumstances with which they have to work and I've been extremely impressed with people at all levels of the FDA involved with CDRH and have enjoyed working with them. Thank you.

MS. THORNTON: Thank you, Joel. We have enjoyed very much working with you and we're sorry to have had to have you for Chair for such a short time.

It's been a pleasure working with all of you and I'd like to welcome again our new consultants to the table and our new industry rep and hopefully this hasn't been total shock treatment, but you'll be willing to come back and help us out in the future.

At this time I'd just like to reiterate that we will be having a meeting January 17th and 18th next year. Until that time -- what?

DR. SUGAR: Do you leave the papers?

MS. THORNTON: Yes. I'd like all the -- by the way, but I did want to say until that time I hope that you all have a happy and a safe holiday.

I'd like the Panel to leave all materials that were issued to them to review for this meeting at the table. And please fill out for your benefit at future meetings, please fill out this evaluation form that I left at your table at the beginning of the meeting.

Thank you again.

(Whereupon, at 3:46 p.m. the meeting was adjourned.)

CERTIFICATE

This is to certify that the foregoing transcript in the matter of: Ophthalmic Devices Panel Meeting

Before: DHHS/PHS/FDA/CDRH

Date: November 30, 2001

Place: Gaithersburg, MD

represents the full and complete proceedings of the aforementioned matter, as reported and reduced to typewriting.